

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and following remarks.

I. Status of the Claims

Claims 1-50, 58, 65 – 78, and 82 – 119, were previously cancelled, and claims 51- 57, 59 – 64, 79 – 81, and 120 – 131 are pending for examination on the merits.

Claim 51 has been amended to move a phrase from the preamble of the claim to the body of the claim.

Because the foregoing amendment does not introduce new matter, entry thereof by the Examiner is respectfully requested.

II. The Office Action

A. Rejection of Claims Under 35 U.S.C. § 103

Claims 51 – 57, 59-64, 79-81, and 120-131 are rejected under 35 U.S.C. § 103(a) as being allegedly obvious over Wood et al., U.S. Patent No. 6,264,922 (“Wood”) in view of U.S. Patent No. 6,241,969 to Saidi et al. (“Saidi”). Office Action at pages 2-4. Applicants respectfully traverse this rejection.

1. The Examiner’s Basis for the Rejection

The Examiner alleged that Wood teaches aerosols compositions, and methods of using such compositions, that comprise (1) droplets of 50 microns or less in diameter; (2) water as a dispersion medium; (3) a poorly soluble therapeutic agent having an effective average particle size of less than about 1000 nm. Office Action at pages 2-3. The Examiner also noted that Wood does not teach species of corticosteroids and anti-inflammatory agents. Office Action at page 3.

In response to Applicants’ arguments presented in the Amendment filed on September 23, 2003, regarding the citation of Wood, the Examiner stated that:

- Although Wood is silent regarding the delivery time, this is considered an inherent property of a composition with similar components and limitations;
- Regarding claims 51-57 and 59-64, this argument is not commensurate in scope with the scope of the claims, as these claims recite “suitable for,” which is not considered a positive recitation and is not given weight in the examination of the claims, and the limitation is recited in the preamble of the claim rather than the body; and
- While Wood does not specifically teach the compounds recited in the claims, Wood teaches classes encompassing such compounds, and Saidi teaches the specific species recited in the claims.

In sum, Wood does not teach: (1) the delivery time required by Applicants’ claims, (2) the specific drugs recited in Applicant’s claims; or (3) the property by which each droplet contains at least one drug particles, as required by Applicant’s claims. These deficiencies are not remedied by Saidi.

2. Wood Does Not Teach or Suggest Applicants’ Claimed Short Administration Period

In response to the Examiner’s comments, Applicants have amended claim 51 to delete the administration period from the preamble of the claim, and to add this limitation into the body of the claim.

Wood does not teach or suggest aerosol compositions that can be administered in less than about 15 seconds or methods of administering the same, as required by claims 51 and 79, respectively, or aerosol compositions that can be administered in less than about 1 to 2 seconds or methods of administering the same, as required by claims 52 and 120, respectively.

Moreover, this property is not inherently present in the class of aerosol compositions taught by Wood. For administration of a drug dosage in a very short period of time, the aerosol needs to have a high concentration of drug, such that essentially each droplet of the

aerosol comprises at least one nanoparticulate drug particle. This is not taught or suggested by Wood et al. This is significant as short administration times, such as those encompassed by Applicants' claims, are highly preferred as they can correlate with increased patient compliance, and thereby reduced episodes of asthma or other condition which is being treated with the aerosol composition.

**3. Wood in View of Saidi Do Not Teach or Suggest
the Compounds Required by the Claims**

All of Applicants' claims are limited to compositions, and methods of administering such compositions, comprising naproxen, triamcinolone acetonide, budesonide, or an anti-emetic.

As noted by the Examiner, Wood does not teach the specific compounds recited in Applicant's claims. The general disclosure of therapeutic and diagnostic agents in Wood would not have fairly suggested the claimed invention to the artisan of ordinary skill to the extent that the claims recite specific drugs not disclosed in Wood.

This deficiency is not remedied by Saidi. Saidi is directed to corticosteroid compositions for nasal or pulmonary administration. Examples of corticosteroids given include triamcinolone acetonide and budesonide. This teaching does not suggest that such compounds can be employed in aerosols of nanoparticulate drugs capable of delivering highly concentrated dosages in extremely short time periods. For example, in contrast to the claimed invention, Saidi teaches that "the compositions can be formulated such that they contain the corticosteroid active agent(s) in a dissolved state." (Col. 5, lines 34-35.) All of the Examples of Saidi teach dissolution of the active agent in a solvent, such as TPGS and ethanol, and in fact the claims of this application are limited to dissolved corticosteroids, suggesting that this is the only delivery method that was shown to be enabled by the disclosure. Dissolving active agents in a solvent, particularly for nasal or pulmonary delivery, is highly undesirable as such solvents can irritate mucus membranes. This is in contrast to the claimed invention, which utilizes aqueous aerosols.

For at least these reasons, Wood in view of Saidi do not teach or suggest the claimed invention. Withdrawal of this ground for rejection is respectfully requested.

B. Provisional Obviousness-Type Double Patenting

Claims 51-57, 59-64, 79-81, and 120-131 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims of copending Application No. 09/190,138 for reasons set forth in the Office Action dated October 2, 2002.

Applicants thank the Examiner for agreeing to hold this rejection in abeyance until such time as allowable subject matter has been indicated.

IV. Conclusion

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. If the Examiner believes that a telephone interview would advance the prosecution of the present application, she is invited to contact the undersigned by telephone.

Respectfully submitted,

Date March 1, 2004

By Michele M. Simkin

FOLEY & LARDNER
Customer Number: 22428
22428

Michele M. Simkin
Attorney for Applicant
Registration No. 34,717

22428

PATENT TRADEMARK OFFICE

Telephone: (202) 672-5538
Facsimile: (202) 672-5399

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.